

BEST AVAILABLE COPY

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
13 November 2003 (13.11.2003)

PCT

(10) International Publication Number
WO 03/092520 A1

(51) International Patent Classification⁷: **A61B 18/12** (74) Agents: DENNINGER, Douglas, E.; Tyco Healthcare Group LP, 10 Glover Avenue, Norwalk, CT 06850 et al. (US).

(21) International Application Number: PCT/US03/14155

(22) International Filing Date: 6 May 2003 (06.05.2003)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/378,290 6 May 2002 (06.05.2002) US
60/392,008 26 June 2002 (26.06.2002) US

(71) Applicant (for all designated States except US): SHERWOOD SERVICES AG [CH/CH]; Bahnhofstrasse 29, CH-8200 Schaffhausen (CH).

(72) Inventor; and

(75) Inventor/Applicant (for US only): PODHAJSKY, Ronald, J. [US/US]; 6941 Harvest Road, Boulder, CO (US).

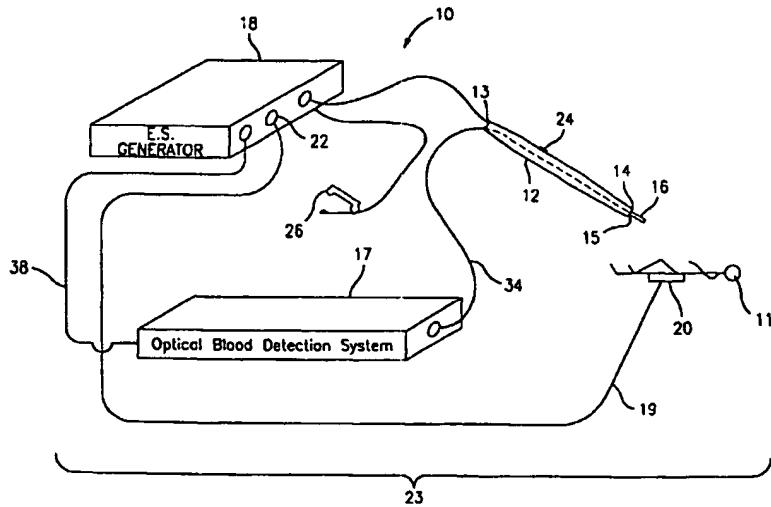
(81) Designated States (national): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, OM, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States (regional): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, BE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:
— with international search report

[Continued on next page]

(54) Title: BLOOD DETECTOR FOR CONTROLLING ANESU AND METHOD THEREFOR



WO 03/092520 A1

(57) Abstract: A method and electrosurgical system for optically detecting blood and controlling an electrosurgical generator are provided. An optical blood detection system is used for optically detecting blood and may be included as an integral part of the overall electrosurgical system's circuitry, or may be designed as a separate unit that connects to, and controls, an electrosurgical generator. The optical blood detection system may be embodied through a variety of analog, digital and/or optical circuit components or arrangements, including software running on computational and memory circuitry. The optical blood detection system controls the output mode and energy of the electrosurgical generator in accordance with the amount of blood detected.

WO 03/092520 A1



For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

BLOOD DETECTOR FOR CONTROLLING ANESU AND METHOD THEREFOR

PRIORITY

5 This application claims priority to a U.S. Provisional Application filed on May 6, 2002 and assigned U.S. Provisional Application Serial No. 60/378,290, the entire contents of which are incorporated herein by reference.

BACKGROUND**1. Technical Field**

10 The disclosure relates to electrosurgery combined with optical detection of blood, and more particularly the automatic control of the level of electrosurgical energy to be delivered to tissue in accordance with the amount of blood optically detected.

2. Description of the Related Art

15 Electrosurgery involves the application of radio frequency energy to achieve a tissue effect. An electrosurgical generator is used in surgical procedures to deliver electrical energy to the tissue of a patient. An electrosurgical generator often includes a radio frequency generator and its controls. When an electrode is connected to the generator, the electrode can be used for cutting or coagulating the tissue of a patient with high frequency electrical energy. During normal operation, alternating electrical 20 current from the generator flows between an active electrode and a return electrode by passing through the tissue and bodily fluids of a patient.

The electrical energy usually has its waveform shaped to enhance its ability to cut or coagulate tissue. Different waveforms correspond to different modes of operation of the generator, and each mode gives the surgeon various operating 25 advantages. Modes may include cut, coagulate, a blend thereof, or desiccate. A surgeon can easily select and change the different modes of operation as the surgical procedure progresses.

In each mode of operation, it is important to regulate the electrosurgical energy delivered to the patient to achieve the desired surgical effect. This can be done, for 30 example, by controlling the output energy from the electrosurgical generator for the type of tissue being treated.

Different types of tissues will be encountered as the surgical procedure progresses and each unique tissue requires more or less energy in terms of voltage, current or power as a function of frequently changing tissue impedance and other factors, such as the level of vascularization, i.e., blood flow within the tissue.

- 5 Therefore, the same tissue will present different load impedance as the tissue is desiccated.

Two conventional types of energy regulation are used in commercial electrosurgical generators. The most common type controls the DC power supply of the generator by limiting the amount of power provided from the AC mains to which the 10 generator is connected. A feedback control loop regulates output voltage by comparing a desired voltage or current with the output voltage or current supplied by the power supply. Another type of power regulation in commercial electrosurgical generators controls the gain of the high-frequency or radio frequency amplifier. A feedback control loop compares the output power supplied from the RF amplifier for adjustment 15 to a desired power level.

U.S. Patent Nos. 3,964,487; 3,980,085; 4,188,927 and 4,092,986 have circuitry to reduce the output current in accordance with increasing load impedance. In those patents, constant voltage output is maintained and the current is decreased with increasing load impedance.

20 U.S. Patent No. 4,126,137 controls the power amplifier of the electrosurgical unit in accord with a non-linear compensation circuit applied to a feedback signal derived from a comparison of the power level reference signal and the mathematical product of two signals including sensed current and voltage in the unit.

U.S. Patent No. 4,658,819 has an electrosurgical generator which has a 25 microprocessor controller based means for decreasing the output power as a function of changes in tissue impedance.

U.S. Patent No. 4,727,874 includes an electrosurgical generator with a high frequency pulse width modulated feedback power control wherein each cycle of the generator is regulated in power content by modulating the width of the driving energy 30 pulses.

U.S. Patent No. 3,601,126 has an electrosurgical generator having a feedback circuit that attempts to maintain the output current at constant amplitude over a wide range of tissue impedances.

None of the aforementioned U.S. patents include optical detection of blood for regulating or controlling the output energy or output waveforms of the electrosurgical generator during different operational modes over a finite patient tissue impedance range. Optical detection of blood during electrosurgery also allows surgeons with color blindness to effectively perform electrosurgery. In a study that was published in 1997, 18 of 40 physicians with color blindness reported difficulties in detecting blood in body products. Spalding, J. Anthony B., "Doctors with inherited colour vision deficiency: their difficulties in clinical work," Cavonius CR, ed., Colour Vision Deficiencies, XII: Proceeding of the International Research Group for Colour Vision Deficiencies, 1995, Norwell, Mass.: Kluwer Academic Publishers, pages 483-489, 1997.

Accordingly, there exists a need for a method and system for optically detecting blood during electrosurgery and controlling the output energy or output waveforms of an electrosurgical generator in accordance with the amount of blood optically detected.

SUMMARY

A method and electrosurgical system for optically detecting blood and controlling an electrosurgical generator are provided. An optical blood detection system is used for optically detecting blood and may be included as an integral part of the overall electrosurgical system's circuitry, or may be designed as a separate unit that connects to, and controls, an electrosurgical generator. The optical blood detection system may be embodied through a variety of analog, digital and/or optical circuit components or arrangements, including software running on computational and memory circuitry.

The optical blood detection system controls the output energy of the electrosurgical generator in accordance with the amount of blood detected. This allows for a surgeon to perform electrosurgery without having to stop and observe the condition of the tissue to determine if additional electrosurgery is needed.

More particularly, the optical blood detection system automatically controls the output waveform generated by the electrosurgical generator during electrosurgery using a feedback signal received from the optical blood detection system. For example, if coagulation of the tissue is desired, the optical blood detection system continuously analyzes the tissue for the presence of blood and controls the output waveform accordingly.

While the optical blood detection system may be used to control electrosurgical generators of varying designs, it is preferred that the electrosurgical generator includes a power selection system wherein the user may initialize, set, monitor, and/or control the operation of the electrosurgical generator. The preferred electrosurgical generator need not be limited to these four functional elements, for example the electrosurgical generator could also include additional safety, monitoring, signal modification/conditioning, and/or feedback circuitry or functional elements/processes. The actual electrosurgical generator's design may include the use of digital components and signaling, analog components and signaling, and/or optical components and signaling, or may be embodied, completely or partially within a software process running on hardware components.

The optical blood detection system includes an optical light beam generating circuit having optical components for generating and focusing a light beam in close proximity to and/or on an electrode of an electrosurgical instrument; a circuit having optical components for capturing reflected light energy, such as a photosensitive detector; a blood detection circuit for analyzing the reflected light energy and/or other characteristics and determining the amount of blood present in proximity to and/or on the electrode; and a feedback correction circuit.

The feedback correction circuit which is electrically connected to receive a signal from the blood detection circuit functions to produce a feedback control signal which it then supplies to the power selection system, within the electrosurgical generator, so as to cause the power selection system to control the amount of electrosurgical energy created and/or the type of output waveform generated in accordance to the amount of blood present in proximity to and/or on the electrode. The system can also detect the presence of any blood vessels in proximity to the distal end

of the electrode and control the electrosurgical generator accordingly or alert the surgeon to prevent, for example, the severing of major blood vessels.

Preferably, the optical light beam is focused in front of the distal end of the electrode to detect blood present on tissue which is being cut or coagulated by the 5 electrosurgical instrument. The optical light beam may have light energy within the visible, near-infrared and infrared light spectrum wavelengths.

It is provided that one or more of the above-mentioned circuits can be implemented by one or more sets of programmable instructions configured for being executed by at least one processor of the electrosurgical system or at least one processor 10 remotely located from the electrosurgical system. For example, the data corresponding to the reflected light energy can be transmitted, either wirelessly or non-wirelessly, over a network, such as a LAN, WAN, or the Internet, to a remote server or control station for analyzing the data using a set of programmable instructions for determining the amount of blood present in proximity to and/or on the electrode.

15 In accordance with the analysis performed, the remote server or control station then generates using the same or another set of programmable instructions the feedback control signal and supplies the signal to the power selection system. It is contemplated that another form of electromagnetic energy can be used to detect for the presence of blood besides the optical beam of light.

20 In one embodiment of the present invention an electrosurgical system is provided which includes a handpiece having a proximal end and a distal end from which light energy is emitted therefrom; at least one electrosurgical electrode on the handpiece and extending from the distal end from which electrosurgical energy is emitted there from; a source of light energy for generating the light energy and 25 transmitting the same to the distal end via at least one waveguide; a source of electrosurgical energy for generating the electrosurgical energy and transmitting the same by at least one electrically conductive element to the electrode; and means for analyzing light energy characteristics for determining the amount of blood present in proximity to the electrode and for controlling the source of electrosurgical energy 30 accordingly.

In another embodiment of the present invention an electrosurgical system is provided which includes means for generating and directing light energy on tissue; means for generating electrosurgical energy and transmitting the same via an electrode to the tissue; and means for analyzing characteristics of the light energy for determining 5 the amount of blood present in proximity to the electrode and for controlling the means for generating electrosurgical energy accordingly.

Further, in another embodiment of the present invention, a method is provided for performing electrosurgery. The method includes the steps of supplying light energy and electrosurgical energy to tissue via at least one instrument having a distal end; and 10 analyzing characteristics of the light energy for determining the amount of blood present in proximity to the at least one instrument and for controlling the delivery of electrosurgical energy accordingly.

Finally, in another embodiment of the present invention, a surgical method is provided which includes the steps of providing a surgical instrument configured for 15 insertion within a patient; providing a source of light energy for generating light energy and delivering the same via the surgical instrument; and analyzing light energy characteristics for determining the amount of blood present in proximity to the surgical instrument.

Further features of the disclosure will become more readily apparent to those 20 skilled in the art from the following detailed description taken in conjunction with the drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Various embodiments will be described hereinbelow with reference to the drawings wherein:

FIG. 1 is a perspective diagram of one embodiment of the present
5 electrosurgical system;

FIG. 2 is cut-away, schematic diagram of an electrosurgical handpiece
instrument of the electrosurgical system of FIG. 1;

FIG. 3 is a block diagram of the optical blood detection system;

FIG. 4 is a flow chart showing the operation of the optical blood detection
10 system according to a first method;

FIG. 5 is a flow chart showing the operation of the optical blood detection
system according to a second method; and

FIG. 6 is a cut-away, schematic diagram of another embodiment for the
electrosurgical handpiece instrument.

15

DETAILED DESCRIPTION OF A PREFERRED EMBODIMENT

An electrosurgical system 10 is shown in perspective in FIG. 1 and allows a surgeon to provide cutting, coagulating, and/or a combination thereof on tissue of a patient 11. The electrosurgical system 10 has a handpiece 12 with a proximal end 13 to
20 be held and controlled by the surgeon. A distal end 14 on the handpiece 12 has a port 15 from which an optical light beam is directed to the patient 11. An electrosurgical electrode 16 extends from the distal end 14 of the handpiece 12.

An optical blood detection system 17 for generating the optical light beam is connected to the proximal end 13 of the handpiece 12 via waveguide/wires 34. The
25 optical blood detection system 17 can be manually controlled by the surgeon or automatically controlled for delivering the optical light beam from the distal end 14 of the handpiece 12 toward the patient 11. An electrosurgical generator 18 for generating the electrosurgical energy is electrically connected to the proximal end 13 of the handpiece 12 and may be manually controlled by the surgeon or automatically
30 controlled for transmitting electrosurgical energy from the electrosurgical electrode 16 toward the patient 11. The optical blood detection system 17 and the electrosurgical

generator 18 are connected by a cable 38 for providing data communications there between and a feedback control signal from the optical blood detection system 17 to the generator 18 for controlling the generator 18.

While the optical blood detection system 17 may be used to control 5 electrosurgical generator 18, it is preferred that the electrosurgical generator 18 includes a power selection system wherein the user may initialize, set, monitor, and/or control the operation of the electrosurgical generator 18. The preferred electrosurgical generator need not be limited to these four functional elements, for example the electrosurgical generator 18 could also include additional safety, monitoring, signal 10 modification/conditioning, and/or feedback circuitry or functional elements/processes. The actual electrosurgical generator's design may include the use of digital components and signaling, analog components and signaling, and/or optical components and signaling, or may be embodied, completely or partially within a software process running on hardware components.

15 A return path 19 is provided for the electrosurgical energy; the return path 19 may be in a monopolar or bipolar circuit. FIG. 1 illustrates a monopolar circuit having a return pad 20, in lieu of a return electrode in the case of a bipolar circuit. The return path 19 is connected to receive at least a portion of the transmitted electrosurgical energy from the source of electrosurgical energy 18 and then the patient 11. A return 20 input 22 for the source of electrosurgical energy 18 is connected to the return path 19 for furnishing a complete circuit 23 between the electrosurgical electrode 16, the patient 11, and the electrosurgical generator 18.

A manually-actuated control button 24 is provided on the handpiece 12 for the selective control by the surgeon of the electrosurgical generator 18 for controlling the 25 electrosurgical energy delivered from the distal end 14. The control button 24 may also be located at a foot pedal 26.

It is provided that the surgeon can utilize the optical beam emanating from port 15 to pinpoint the target tissue to be treated if the optical light beam has light energy within the visible spectrum. It is envisioned that the optical light beam may have light 30 energy within the visible, near-infrared and infrared light spectrum wavelengths.

With reference to FIG. 3, the optical blood detection system 17 includes an optical light beam generating circuit 52 having optical components for generating and focusing a light beam, such as a laser light beam, as known in the art, in close proximity to and/or on the electrode 16 of the handpiece 12. The wave guide 34, shown in FIG. 1, 5 is used to deliver the light energy from the proximal end 13 to beyond the distal end 14. The optical blood detection system 17 further includes at least one optical component 54 positioned at the distal end 14 of the handpiece 12, for capturing reflected light energy as known in the art. The at least one optical component 54 returns signals indicative of the reflected light energy to the system 17 via waveguide/wires 34 to at 10 least one photosensitive detector.

The optical blood detection system 17 further includes a blood detection circuit 56 for analyzing the reflected light energy and determining the amount of blood present in proximity to and/or on the electrode 16; and a feedback correction circuit 58.

The reflected light energy preferably includes data corresponding to light 15 reflections indicative of two different wavelengths, a first and a second wavelength. First, a first optical light beam having the first wavelength is generated and emanated from the handpiece 12. The reflected light energy indicative of the first optical light beam is captured and analyzed by the optical blood detection system 17 for measuring various parameters, such as photon counts. Second, a second optical light beam having 20 the second wavelength is generated and emanated from the handpiece 12. The reflected light energy indicative of the second optical light beam is captured and analyzed by the optical blood detection system 17 for measuring various parameters, such as photon counts.

Alternatively, a broadband optical light beam is generated and emanated from 25 the handpiece 12. The reflected light energies indicative of two separate and distinct wavelengths are captured and analyzed by the optical blood detection system 17 for measuring various parameters, such as photon counts. Preferably, in either method, the first wavelength is in the range of 620-700 nanometers and the second wavelength is in the range of 540-610 nanometers or 950-1050 nanometers.

30 A ratio is then obtained using two measured values corresponding to a particular parameter; one measured value is indicative of the first optical light beam or

wavelength and one measured value is indicative of the second optical light beam or wavelength. A look-up table or other data structure is then used by a processor or by an individual to correlate the ratio with a particular amount or level of blood present in proximity to the electrode 16.

5 The reflected light energy can also be analyzed for determining the amount of blood present using one of several known methods, such as Near Infrared Spectroscopy (NIRS), Infrared Spectroscopy (IRS), Fluorescence Spectroscopy, Raman Spectroscopy, Photoacoustic Spectroscopy (where the system 10 is equipped with a microphone for measuring an acoustic pressure wave created by the optical beam rapidly heating the
10 tissue), laser Doppler flowmetry, light scatter change measurements, and polarization
change measurements. These methods determine the light intensity level, light scattering effects, level of fluorescent energy, and other characteristics of the reflected light energy. The determined light intensity level, light scattering effects, level of fluorescent energy, and/or other characteristics of the reflected light energy are then
15 used to compute using mathematical equations, algorithms, and/or programmable instructions executed by at least one processor the amount of blood present in proximity to the electrode 16.

By knowing the optical signal characteristics of the generated light beam and the determined light intensity level, light scattering effects, level of fluorescent energy, and other characteristics of the reflected light energy, the system 17 is able to determine
20 using a look-up table or other data structure the amount of blood present in proximity to the electrode 16. If the analysis indicates that there is a high amount of blood present in proximity to the electrode 16, one can conclude that the tissue has not coagulated (in the case of a coagulation procedure) or has been cut (in the case of a cutting procedure).
25 If the analysis indicates that there is a low amount of blood present in proximity to the electrode 16, one can conclude that the tissue has coagulated (in the case of a coagulation procedure) or has not been adequately cut (in the case of a cutting procedure).

The system can also detect the presence of any blood vessels in proximity to the
30 distal end of the electrode 16 and control the electrosurgical generator 18 accordingly or alert the surgeon to prevent, for example, the severing of major blood vessels.

The feedback correction circuit 58 which is electrically connected to receive a signal from the blood detection circuit 56 functions to produce a feedback control signal which it then supplies to the power selection system, within the electrosurgical generator 18, via wire 38 so as to cause the power selection system to control the amount of electrosurgical energy created and/or the type of output waveform generated (coagulation or tissue division waveform) in accordance to the amount of blood present in proximity to and/or on the electrode 16.

FIG. 4 is a flow chart illustrating an exemplary method of operation of the optical blood detection system 17. In step 400, the optical light beam and electrosurgical energy are generated. The reflected light energy is captured in step 402 and analyzed in step 404 to determine the amount of blood present in proximity to the electrode 16 at step 406. In step 408 it is determined whether the sensed level of blood in proximity to the electrode 16 is above a predetermined threshold (the predetermined threshold value is dependent on the method being used to detect the amount of blood present). If the sensed level of blood is not above the predetermined threshold value, it is then determined at step 410 whether the procedure being performed is a coagulation procedure. If a coagulation procedure is not being performed, i.e., a cutting procedure is being performed, the cutting procedure is continued at step 412, and the process returns to step 408.

If at step 410, it is determined that a coagulation procedure is being performed, the process proceeds to step 414 where a signal is transmitted by the feedback correction circuit 58 to the electrosurgical generator 18 to control the amount of electrosurgical energy and/or the type of output waveform generated or to shut-off the electrosurgical generator 18, since the coagulation procedure has been adequately performed. If at step 408, it is determined that the sensed level of blood is above the predetermined threshold value, it is then determined at step 416 whether the procedure being performed is a cutting procedure. If a cutting procedure is not being performed, i.e., a coagulation procedure is being performed, the coagulation procedure is continued at step 418, and the process returns to step 408.

If at step 416, it is determined that a cutting procedure is being performed, the process proceeds to step 414 where a signal is transmitted by the feedback correction

circuit 58 to the electrosurgical generator 18 to control the amount of electrosurgical energy and/or the type of output waveform generated or to shut-off the electrosurgical generator 18, since the cutting procedure has been adequately performed.

FIG. 5 is a flow chart illustrating another exemplary method of operation of the optical blood detection system 17. In step 500, the optical light beam and electrosurgical energy are generated. The reflected light energy is captured in step 502 and analyzed in step 504 to determine the amount of blood present in proximity to the electrode 16 at step 506. Step 506 determines the amount of blood present by calculating the ratio value as determined by dividing the photon counts at wavelength 1 by the photon counts at wavelength 2. The ratio value is analyzed at step 508.

If the ratio value is low (lower than a predetermined ratio value) then the process proceeds to step 510 where a signal is transmitted by the feedback correction circuit 58 to the electrosurgical generator 18 to control the mode of operation, namely, selecting a tissue division (cut) mode. Also, the amount of electrosurgical energy may be adjusted.

If at step 508, it is determined that the ratio value is high (greater than the predetermined ratio value), the process proceeds to step 512 where a signal is transmitted by the feedback correction circuit 58 to the electrosurgical generator 18 selecting a hemostasis (coagulation) mode. The amount of electrosurgical energy may also be adjusted.

If at step 508, it is determined that the ratio value is at an intermediate value (approximately equal to the predetermined ratio value), the process proceeds to step 514 where a signal is transmitted by the feedback correction circuit 58 to the electrosurgical generator 18 selecting a blended mode that is in proportion to the detected ratio value. Following either step 510, 512, or 514, the process returns to capture reflected light energy in step 502 in a continuous loop.

It is provided that depending on which of the above spectroscopy and other methods is used by the optical blood detection system 17 to determine the amount of blood present, the optical blood detection system 17 is controlled accordingly using known blood-related optical measurement parameters for each method, in order to generate and focus an optical light beam having characteristics suitable for the method. The optical blood detection system 17 can change the wavelength of the optical light

beam within the visible, near-infrared and infrared light spectrum wavelengths depending on which of the above methods is being used for determining the amount of blood present in proximity to the electrode 16. For example, if the NIRS method is used, the optical light beam needs to have a wavelength just above the visible spectrum.

5 The wavelength of the optical light beam can be manually selected using a control knob or other control means on the optical blood detection system 17. If the wavelength of the optical light beam is in a particular range, the light energy of the optical light beam can be used to create an ionized conductive pathway along which the electrosurgical energy can be guided.

10 When the light energy is being used to create an ionized pathway, the light energy must be controlled using the control means in order to avoid undesired tissue effects. The duty cycle of the light beam should be kept in the range of 10^{-5} to 10^{-8} . Energy density delivered to any single area of tissue from the light beam should not exceed 26 J/cm^2 for wavelengths between 1.06 and 10.6 microns, and 17 J/cm^2 for 15 wavelengths around and below 0.53 microns. For creating the ionized pathway, the wavelength of the optical beam should be in the range of 0.3 to 10.6 microns.

15 It is further provided that one or more of the above-mentioned circuits 52, 56 and 58 can be implemented by one or more sets of programmable instructions configured for being executed by at least one processor of the electrosurgical system 10 or at least one processor remotely located from the electrosurgical system 10. For 20 example, the data corresponding to the reflected light energy can be transmitted, either wirelessly or non-wirelessly, over a network, such as a LAN, WAN, or the Internet, to a remote server or control station for analyzing the data using a set of programmable instructions for determining the amount of blood present in proximity to and/or on the 25 electrode 16 and/or the presence of blood vessels in proximity to the distal end of the electrode 16.

In accordance with the analysis performed, the remote server or control station 30 then generates using the same or another set of programmable instructions the feedback control signal and supplies the signal to the power selection system. It is contemplated that another form of electromagnetic energy can be used to detect for the presence of blood besides the optical beam of light.

Another embodiment for a handpiece for the electrosurgical system 10 is depicted by FIG. 6 and designated generally by reference numeral 12A. The handpiece 12A includes a proximal end 13A which is held and controlled by the surgeon. A distal end 14A on the handpiece 12A has a port 15A from which an optical light beam is directed to the patient 11. An electrosurgical electrode 16A extends from the distal end 14A of the handpiece 12A. The at least one optical component 54 at the distal end 14A of the handpiece 12A returns signals indicative of the reflected light energy to the optical blood detection system 17 via waveguide/wires 34 to at least one photosensitive detector.

A manually-actuated variable control button 24A is provided on the handpiece 12A for the real-time, selective control by the surgeon of the intensity or level of the current, i.e., intensity of the output waveform, provided by the electrosurgical generator 18 in accordance with the amount of blood detected by the optical blood detection system 17. Accordingly, the handpiece 12A provides the surgeon with the ability to control the amount of tissue cutting, coagulating, etc. as the system 10 concurrently detects the amount of blood.

In another preferred embodiment with continued reference to FIG. 6, the optical detection of the presence of blood controls the mode of the electrosurgical generator output in real-time or on-the-fly. For illustrative purposes, if a large amount of blood is detected adjacent to the electrode 16A then the electrosurgical generator output mode is automatically set for a high-level "hemostasis" (coag) waveform. If no blood is detected, then a "tissue division" (cut) waveform is automatically selected for the electrosurgical generator output. If an intermediate amount of blood is detected, then a "blend" is selected in proportion to the amount of blood detected. Simultaneously, the surgeon can use the manually-actuated variable control button 24A for real-time, selective control of the intensity or level of current.

The surgeon selects the intensity that provides an operational speed within his individual comfort zone. So the selection of the mode is automatically controlled by the blood detection circuit 56 and the surgeon controls the intensity of the output in real-time or on-the-fly. This embodiment greatly simplifies the surgeon-equipment interface by providing an automated mode select to assist the surgeon. As a result there

is an improvement in the surgical outcome, because the appropriate mode is selected in real-time, thereby reducing thermal spread within the tissue. Additionally, since the surgeon maintains control of the intensity of the current, there is a built-in safety feature.

5 The above-described control scheme can be offered as a selectable feature or option. That is, a selectable switch would allow the surgeon to choose between operating the system of the present invention in a fully automatic mode or in a mode which enables the surgeon to control the intensity of the current.

10 It is contemplated that the control button 24A may also be located at the foot pedal 26. It is further contemplated that the functions of the variable control button 24A can be automated, in order for the system 10 to automatically control the intensity of the current in accordance with the amount of blood detected by the optical blood detection system 17.

15 It is provided that the surgeon can utilize the optical beam emanating from port 15A to pinpoint the target tissue to be treated if the optical light beam has light energy within the visible spectrum. It is envisioned that the optical light beam may have light energy within the visible, near-infrared and infrared light spectrum wavelengths.

20 As shown by FIGS. 2 and 6, the electrosurgical system 10 is configured so the distal end 14, 14A and the electrosurgical electrode 16, 16A are preferably arranged geometrically relative to the handpiece 12, 12A to provide the light energy from the distal end 14, 14A. This geometry provides for the combined concurrent application of the light energy and the electrosurgical energy. The ionized pathway is formed by the light energy from the distal end 14, 14A to the patient 11 to direct the electrosurgical energy there along.

25 A method for providing cutting, coagulating, and/or a combination thereof on tissue of the patient 11 with the electrosurgical system 10 includes the following step of directing light energy and electrosurgical energy from the handpiece 12, 12A with its proximal and distal ends, 13, 13A and 14, 14A, along a longitudinal axis of the handpiece 12, 12A by aiming the distal end 14, 14A thereof along the longitudinal axis from which light energy and electrosurgical energy may be at least in part concurrently directed.

Preferably, as shown by FIGS. 2 and 6, the optical light beam is focused in front of the distal end 14, 14A of the electrode 16, 16A to detect blood present on tissue which is being cut or coagulated by the handpiece 12, 12A. The light energy is emanated continuously from the distal end 14, 14A of the handpiece 12, 12A. Or, 5 alternatively, the surgeon activates the electrosurgical generator 18 using the control button 24, 24A on the handpiece 12, 12A or the footswitch 26. When activation is initiated, first, light energy is emitted from the distal end 14, 14A of the handpiece 12, 12A, then after a brief time delay in which the presence of blood is detected, the transmission of electrosurgical energy from the electrosurgical electrode 16, 16A at the 10 distal end 14, 14A of the handpiece 12, 12A is enabled.

In the case of encountering a bleeding vessel that has created a pool of blood, this method provides detection of the pool of blood and automatic select of a hemostatic (coagulation) waveform by the electrosurgical generator 18 in order to affect a "spot coag" procedure.

15 Likewise, if no blood is present, the detection system selects a tissue division (cut) waveform. In this way, the thermal damage to the tissue is reduced creating a superior tissue effect.

The method includes the additional step of guiding the electrosurgical energy by arranging the distal end 14, 14A and the electrosurgical electrode 16, 16A geometrically relative to the handpiece 12, 12A for providing the optical light beam from the distal 20 end 14, 14A for the combined concurrent application of the optical light beam and the electrosurgical energy. Then the added step of ionizing a conductive pathway with light energy from the distal end 14, 14A to the patient 11 to direct the flow of electrosurgical energy is performed.

25 The method also includes the additional step of providing an elongate electrosurgical electrode support for supporting the electrode 16, 16A for endoscopic or laparoscopic use where a cannula is placed through the patient's body wall.

The claims which follow seek to cover the described embodiments and their equivalents. The concept in its broadest scope covers the system and methods for 30 optically detecting the presence of blood and/or determining the amount of blood detected during electrosurgery. It is to be understood that the concept is subject to

many modifications without departing from the spirit and scope of the claims as recited herein.

Although the subject invention has been described with respect to preferred embodiments, it will be readily apparent to those having ordinary skill in the art to which it appertains that changes and modifications may be made thereto without departing from the spirit or scope of the subject apparatus as defined by the appended claims.
5

IN THE CLAIMS:

1. An electrosurgical system comprising:
 - a handpiece having a proximal end and a distal end from which light energy is emitted therefrom;
 - 5 at least one electrosurgical electrode on the handpiece and extending from the distal end from which electrosurgical energy is emitted there from;
 - a source of light energy for generating the light energy and transmitting the same to the distal end via at least one waveguide;
 - a source of electrosurgical energy for generating the electrosurgical energy and 10 transmitting the same by at least one electrically conductive element to the electrode;
 - and
 - means for analyzing light energy characteristics for determining the amount of blood present in proximity to the electrode and for controlling the source of electrosurgical energy accordingly.
- 15 2. The electrosurgical system of Claim 1, wherein the source of light energy generates light energy in at least one of the visible, near-infrared and infrared light spectrum wavelengths.
- 20 3. The electrosurgical system of Claim 1, wherein the source of electrosurgical energy generates electrosurgical energy having at least one of a tissue division and a coagulation output waveform.
4. The electrosurgical system of Claim 1, wherein the energy 25 characteristics are selected from the group consisting of light intensity level, light scattering effects, and level of fluorescent energy.
5. The electrosurgical system of Claim 1, wherein the means for analyzing is remotely located from the source of light energy and the source of electrosurgical 30 energy.

6. The electrosurgical system of Claim 1, wherein the means for analyzing communicates with the source of light energy via a network.

7. The electrosurgical system of Claim 1, wherein the means for analyzing
5 analyzes light energy characteristics using a method selected from the group consisting of Near Infrared Spectroscopy, Infrared Spectroscopy, Fluorescence Spectroscopy, Raman Spectroscopy, Photoacoustic Spectroscopy, laser Doppler flowmetry, measurement of light scatter changes, and measurement of polarization changes.

10 8. The electrosurgical system of Claim 1, wherein the light energy has a wavelength suitable for creating an ionized pathway between the distal end and the tissue of a patient, and the electrode is positioned near the ionized pathway such that the electrosurgical energy is conducted along the ionized pathway.

15 9. The electrosurgical system of Claim 1, wherein the means for analyzing includes means for detecting the presence of at least one blood vessel in proximity to the distal end of the electrode.

10. The electrosurgical system of Claim 1, wherein the means for analyzing
20 light energy characteristics includes means for determining a ratio value by dividing a first parameter obtained by emitting light energy from the handpiece having a first wavelength from a second parameter obtained by emitting light energy from the handpiece having a second wavelength.

25 11. The electrosurgical system of Claim 10, wherein the means for analyzing light energy characteristics further includes means for determining whether the ratio value is lower than, approximately equal to, or greater than a predetermined ratio value and for controlling the electrosurgical generator accordingly.

12. The electrosurgical system of Claim 10, wherein the first wavelength is in the range of 620-700 nanometers and the second wavelength is in the range of 540-610 nanometers or 950-1050 nanometers.

5 13. The electrosurgical system of Claim 1, wherein the means for analyzing and controlling the source of electrosurgical energy includes means for variably controlling the intensity of the current generated by the electrosurgical generator.

10 14. An electrosurgical system comprising:
means for generating and directing light energy on tissue;
means for generating electrosurgical energy and transmitting the same via an electrode to the tissue; and

15 means for analyzing characteristics of the light energy for determining the amount of blood present in proximity to the electrode and for controlling the means for generating electrosurgical energy accordingly.

15 15. The electrosurgical system of Claim 14, wherein the means for generating and directing light energy generates light energy in at least one of the visible, near-infrared and infrared light spectrum wavelengths.

20 16. The electrosurgical system of Claim 14, wherein the means for generating electrosurgical energy generates electrosurgical energy having at least one of a tissue division and a coagulation output waveform.

25 17. The electrosurgical system of Claim 14, wherein the light energy characteristics are selected from the group consisting of light intensity level, light scattering effects, and level of fluorescent energy.

30 18. The electrosurgical system of Claim 14, wherein the means for analyzing is remotely located from the means for generating light energy and the means for generating electrosurgical energy.

19. The electrosurgical system of Claim 14, wherein the means for analyzing analyzes light energy characteristics using a method selected from the group consisting of Near Infrared Spectroscopy, Infrared Spectroscopy, Fluorescence Spectroscopy, Raman Spectroscopy, Photoacoustic Spectroscopy, laser Doppler flowmetry, 5 measurement of light scatter changes, and measurement of polarization changes.

20. The electrosurgical system of Claim 14, wherein the light energy has a wavelength suitable for creating an ionized pathway between a distal end of the electrode and the tissue, and the electrode is positioned near the ionized pathway such 10 that the electrosurgical energy is conducted along the ionized pathway.

21. The electrosurgical system of Claim 14, wherein the means for analyzing includes means for detecting the presence of at least one blood vessel in proximity to a distal end of the electrode.

15

22. The electrosurgical system of Claim 14, wherein the means for analyzing characteristics of the light energy includes means for determining a ratio value by dividing a first parameter obtained by directing light energy having a first wavelength from a second parameter obtained by directing light energy having a second 20 wavelength.

23. The electrosurgical system of Claim 22, wherein the means for analyzing characteristics of the light energy further includes means for determining whether the ratio value is lower than, approximately equal to, or greater than a predetermined ratio 25 value and for controlling the means for generating electrosurgical energy accordingly.

24. The electrosurgical system of Claim 22, wherein the first wavelength is in the range of 620-700 nanometers and the second wavelength is in the range of 540-610 nanometers or 950-1050 nanometers.

30

25. The electrosurgical system of Claim 14, wherein the means for analyzing and controlling the source of electrosurgical energy includes means for variably controlling the intensity of the current generated by the electrosurgical generator.

5 26. A method for performing electrosurgery, the method comprising the steps of:

supplying light energy and electrosurgical energy to tissue via at least one instrument having a distal end; and

10 analyzing characteristics of the light energy for determining the amount of blood present in proximity to the at least one instrument and for controlling the delivery of electrosurgical energy accordingly.

15 27. The method of Claim 26, wherein the step of analyzing characteristics of the light energy includes the step of using a method selected from the group consisting of Near Infrared Spectroscopy, Infrared Spectroscopy, Fluorescence Spectroscopy, Raman Spectroscopy, Photoacoustic Spectroscopy, laser Doppler flowmetry, measurement of light scatter changes, and measurement of polarization changes.

20 28. The method of Claim 26, further comprising the step of sequencing the delivery of light energy and electrosurgical energy from the distal end for first creating an ionized pathway between the distal end and the tissue, and conducting electrosurgical energy along the ionized pathway.

25 29. The method of Claim 26, wherein the analyzing step further includes the step determining the presence of at least one blood vessel in proximity to the at least one instrument.

30. The method of Claim 26, wherein the step of analyzing characteristics of the light energy includes the step of determining a ratio value by dividing a first parameter obtained by supplying light energy having a first wavelength from a second parameter obtained by supplying light energy having a second wavelength.

31. The method of Claim 30, wherein the step of analyzing characteristics of the light energy further includes the step of determining whether the ratio value is lower than, approximately equal to, or greater than a predetermined ratio value.

5 32. The method of Claim 30, wherein the first wavelength is in the range of 620-700 nanometers and the second wavelength is in the range of 540-610 nanometers or 950-1050 nanometers.

10 33. The method of Claim 26, wherein the step of controlling includes the step of variably controlling the intensity of the current generated by the electrosurgical generator.

15 34. A surgical method comprising the steps of:
providing a surgical instrument configured for insertion within a patient;
providing a source of light energy for generating light energy and delivering the same via the surgical instrument; and
analyzing light energy characteristics for determining the amount of blood present in proximity to the surgical instrument.

1/6

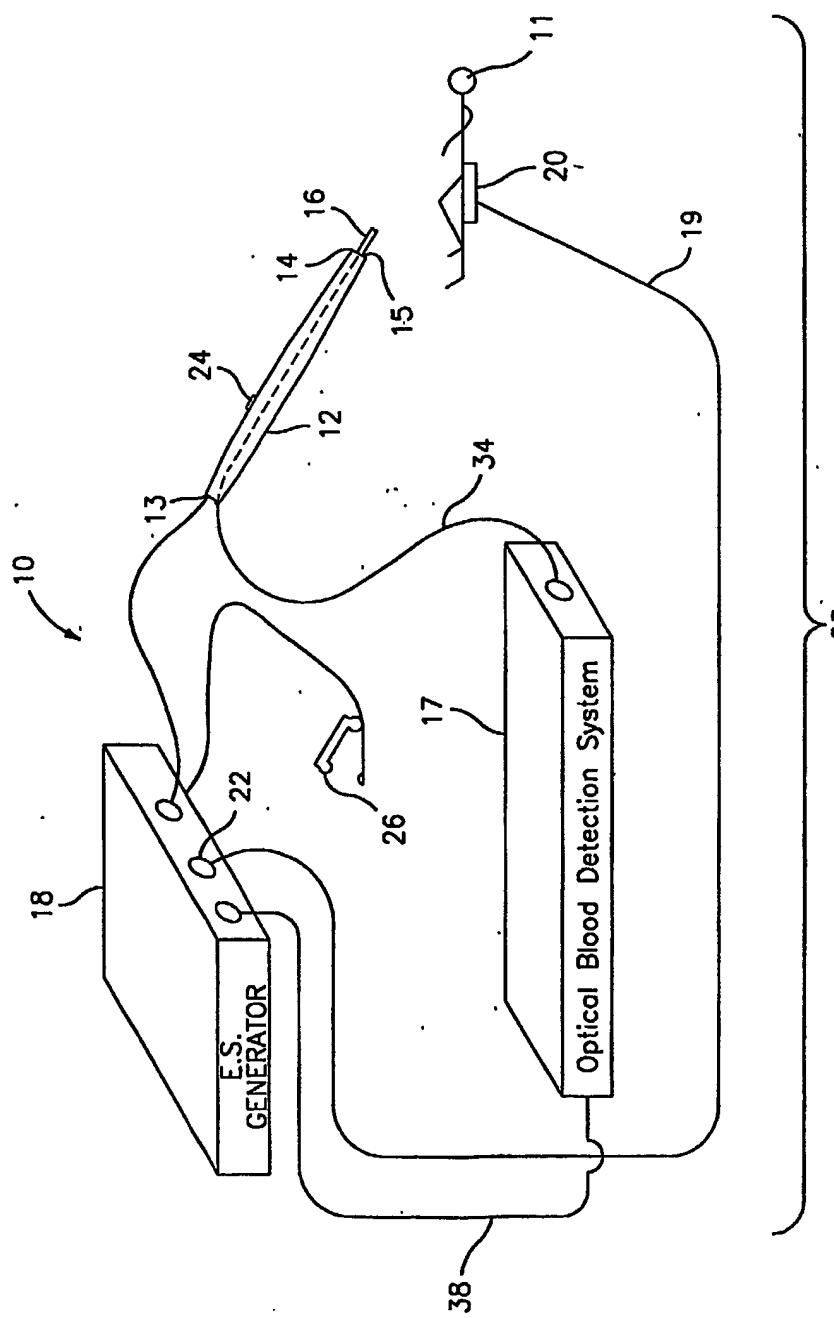


FIG. 1

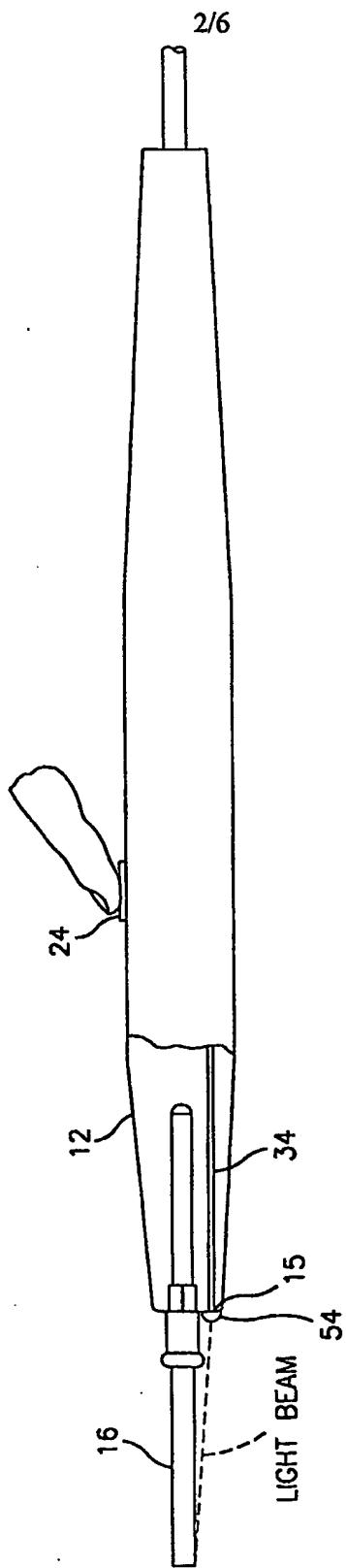


FIG. 2

3/6

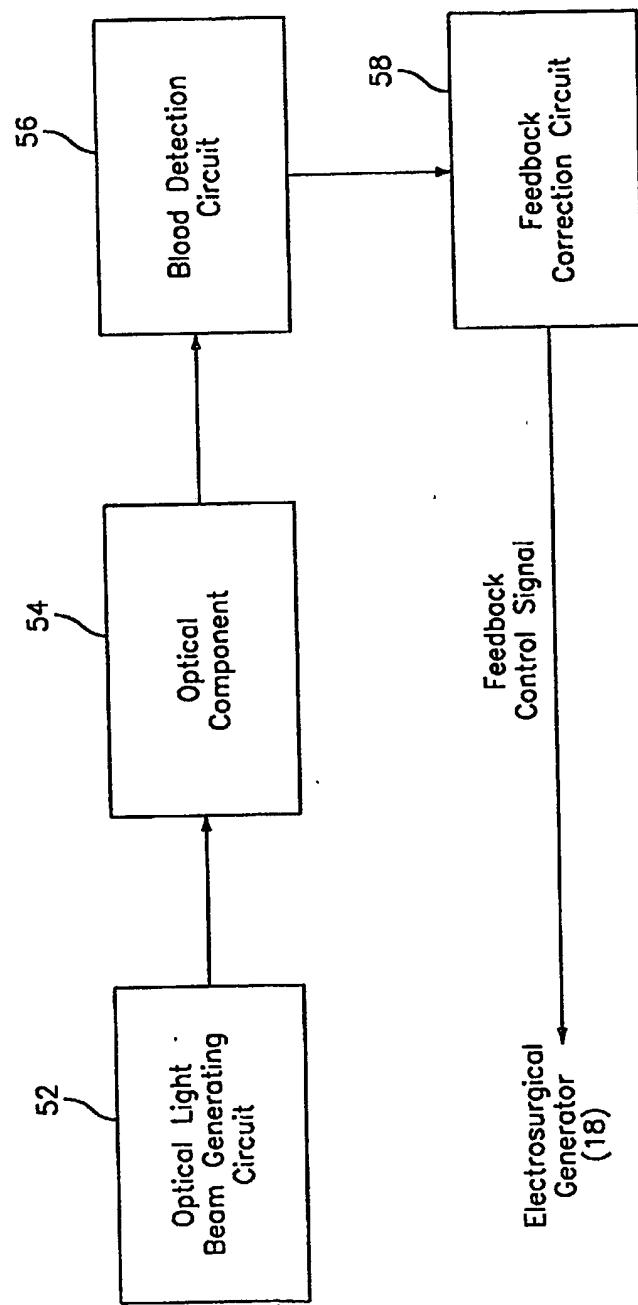


FIG. 3

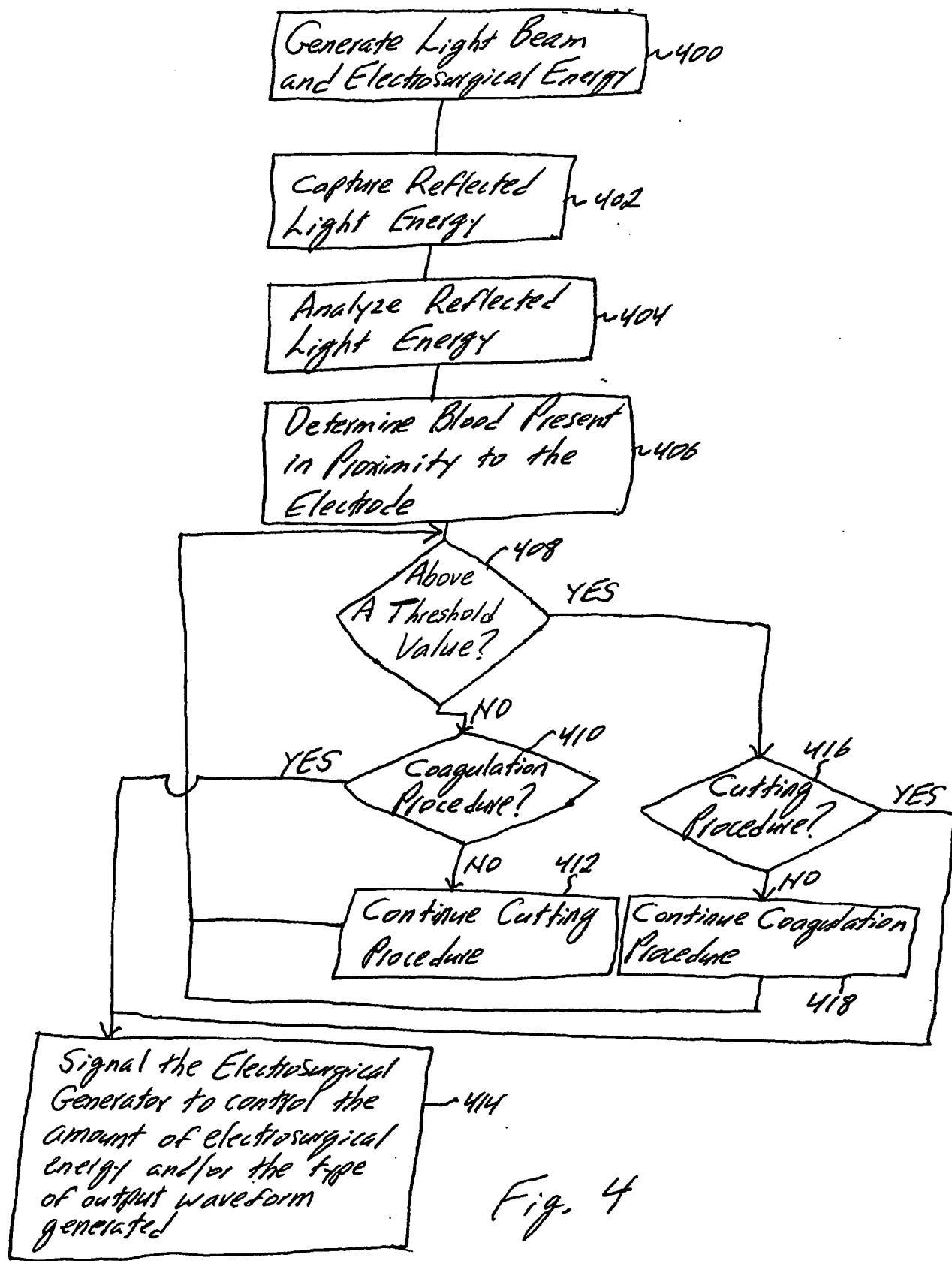


Fig. 4

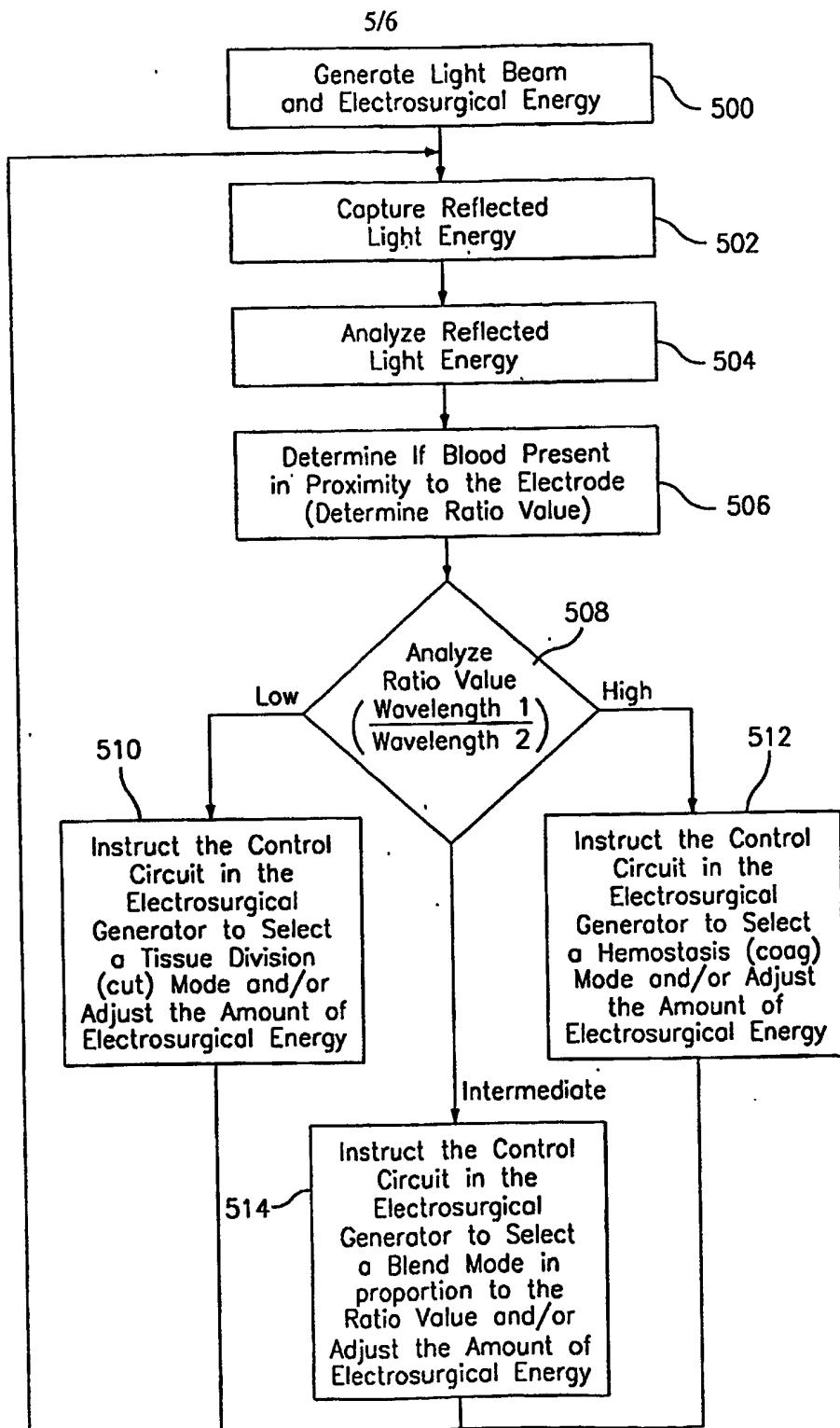


FIG. 5

6/6

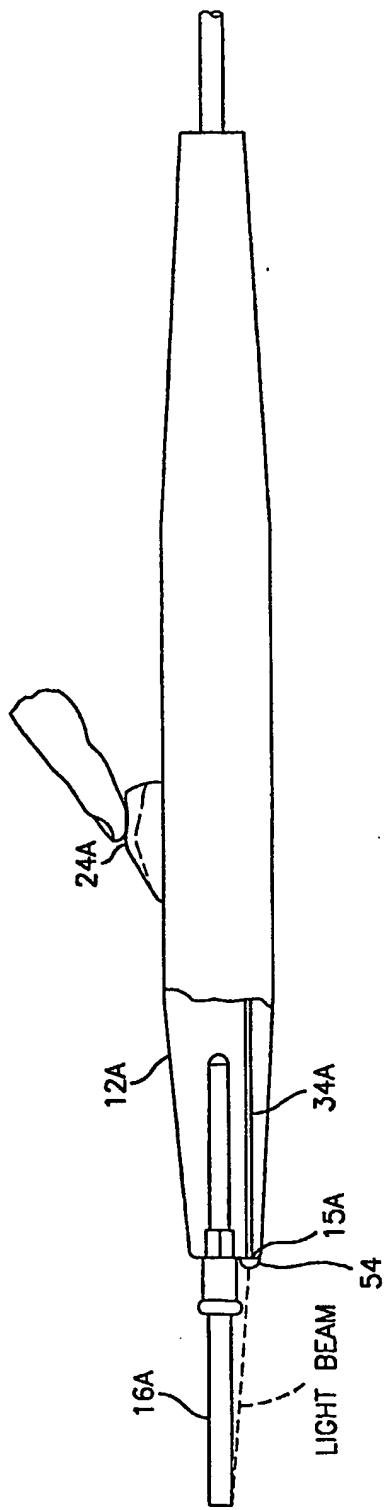


FIG. 6

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 03/14155

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B18/12

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the International search (name of data base and, where practical, search terms used)

EPO-Internal, PAJ, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|----------|---|-----------------------|
| A | US 6 162 217 A (KANNENBERG DONALD P ET AL) 19 December 2000 (2000-12-19) abstract | 1 |
| A | WO 02 11634 A (ERBE ELEKTROMEDIZIN ;HAGG MARTIN (DE)) 14 February 2002 (2002-02-14) abstract | 1 |
| A | US 4 114 604 A (SHAW ROBERT F ET AL) 19 September 1978 (1978-09-19) column 1, line 26-40 | 1 |



Further documents are listed in the continuation of box C.



Patent family members are listed in annex.

* Special categories of cited documents :

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the International filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the International filing date but later than the priority date claimed

- *T* later document published after the International filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- *&* document member of the same patent family

Date of the actual completion of the international search

9 July 2003

Date of mailing of the International search report

17/07/2003

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo NL,
Fax: (+31-70) 340-3016

Authorized officer

Papone, F

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 03/14155

Box I Observations where certain claims were found unsearchable (Continuation of Item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. Claims Nos.: **26–34**
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT – Method for treatment of the human or animal body by surgery
2. Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of Item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- The additional search fees were accompanied by the applicant's protest.
 No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 03/14155

| Patent document cited in search report | | Publication date | | Patent family member(s) | Publication date |
|--|---|------------------|--|---|--|
| US 6162217 | A | 19-12-2000 | AU WO US US | 4205800 A 0062695 A1 2003060818 A1 2001029369 A1 | 02-11-2000 26-10-2000 27-03-2003 11-10-2001 |
| WO 0211634 | A | 14-02-2002 | DE DE WO EP | 10044189 A1 10054963 A1 0211634 A1 1307154 A1 | 07-03-2002 21-03-2002 14-02-2002 07-05-2003 |
| US 4114604 | A | 19-09-1978 | CA CH DE FR GB JP JP JP NL | 1086982 A1 627277 A5 2741981 A1 2368038 A1 1586888 A 1349016 C 53050880 A 61011096 B 7709465 A ,C | 07-10-1980 31-12-1981 20-04-1978 12-05-1978 25-03-1981 28-11-1986 09-05-1978 01-04-1986 20-04-1978 |

**This Page is Inserted by IFW Indexing and Scanning
Operations and is not part of the Official Record**

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- BLACK BORDERS**
- IMAGE CUT OFF AT TOP, BOTTOM OR SIDES**
- FADED TEXT OR DRAWING**
- BLURRED OR ILLEGIBLE TEXT OR DRAWING**
- SKEWED/SLANTED IMAGES**
- COLOR OR BLACK AND WHITE PHOTOGRAPHS**
- GRAY SCALE DOCUMENTS**
- LINES OR MARKS ON ORIGINAL DOCUMENT**
- REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY**
- OTHER:** _____

IMAGES ARE BEST AVAILABLE COPY.

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.

THIS PAGE BLANK (USPTO)